

### **REMARKS**

This Amendment is in response to the Examiner's Answer mailed on 1 June 2010 (an unnumbered Paper) . Reexamination and reconsideration are respectfully requested.

### **Listing of The Claims**

Pursuant to 37 CFR §121(c), the claim listing, including the text of the claims, will serve to replace all prior versions of the claims, in the application.

### **Status of The Claims**

Claims 7, 13, and 19 are pending in this application.

### **Amendment of The Claims**

Claim 19 is amended in this Paper.

### **Issues raised by the Examiner's Answer**

In the Examiner's Answer mailed on 1 June 2010:

- Claims 7, 13 and 19 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement; and
- Claims 7, 13 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cuilleron (FR 2610512 A) in view of Hansson et al. (US 5,588,838).

Applicant respectfully traverses the rejections due to the following reasons.

#### **(1) Rejection of Claims 7, 13 and 19 under U.S.C. §112, first paragraph**

In the Examiner's Answer mailed on 1 June 2010, the Examiner stated:

“Claims 7, 13 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The originally filed specification fails to reasonably describe the claimed subject matter in a manner sufficient to convey to one skilled in the art that applicant had possession of the invention defined by the limitations in claims 7 and 13 that "said recesses being separated by a distance on an order of 150  $\mu\text{m}$ " and in claim 19 the limitation that "the distance between the neighboring micro-patterns being approximately 150  $\mu\text{m}$ ." More particularly, the originally filed specification (page 5, lines 15-25) gives the specific example of 150  $\mu\text{m}$ , but fails to reasonably convey the "on an order of" or the "approximately" limitations that were added during prosecution to modify the "150  $\mu\text{m}$ " limitation."

Respectfully, the Examiner's attention is invited to note that page 5, lines 17-25 of Applicant's original specification reads:

"For example, the pattern may have any size in the range of several dozens of  $\mu\text{m}$  or several hundreds of  $\mu\text{m}$ , such as 30  $\mu\text{m}$ , 50  $\mu\text{m}$ , 80  $\mu\text{m}$ , 100  $\mu\text{m}$ , 150  $\mu\text{m}$ , 250  $\mu\text{m}$  and 300  $\mu\text{m}$ , and has a single shape or a combination of various shapes.

Meanwhile, when the helical implant according to the present invention is fixed in the bone, since a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100  $\mu\text{m}$ , the pattern must be formed to have a size of 100  $\mu\text{m}$  or more, **preferably 150  $\mu\text{m}$ .**"

According to Applicant's original specification, the micro-pattern formed on the thread inclines (i.e., flanks) may have a size in the range of several dozens of  $\mu\text{m}$  or several hundreds of  $\mu\text{m}$ , and may have a minimum size of about 100  $\mu\text{m}$ , **preferably 150  $\mu\text{m}$ .** Apparently, both "several dozens of  $\mu\text{m}$ " and "minimum size of about 100  $\mu\text{m}$ " is "on the order of" and/or "approximately" 150  $\mu\text{m}$ .

Therefore, the language "several dozens of  $\mu\text{m}$ ", "minimum size of about 100  $\mu\text{m}$ " and "preferably 150  $\mu\text{m}$ " of Applicant's original specification clearly defines that the size of the micro-pattern is "one the order of" and "approximately" 150  $\mu\text{m}$ .

Accordingly, the rejection of claims 7, 13 and 19 under U.S.C. §112, first paragraph is improper and should be withdrawn.

**(2) Rejection of Claims 7, 13 and 19 under U.S.C. §103(a)**

**(a) The functionality of Cuilleron '512's implant prevents Cuilleron '512 from forming "helical thread"**

First, as is indicated by a thorough reading of Cuilleron '512, the Examiner's proposed combination fails to teach, or suggest, Applicant's "helical threads." Two observations confirm this omission: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the specification of Cuilleron '512.

How can the administrative record support the Examiner's finding that Cuilleron '512 teaches any peripheral structure except a series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading." Threading may be circular, concentrically circular or even axially oriented. The Examiner's proposed combination is silent on the issue of precisely which adjective modifies "threading."

In the Examiner's Answer mailed on 1 June 2010, the Examiner stated:

"However, even if it were interpreted that Cuilleron only reasonably teaches concentric rings, then the examiner is of the position that the use of conventional helical threading in the Cuilleron implant such as that disclosed Hansson et al would have been obvious to the ordinarily skilled artisan so that one could have "screwed in" the implant into bone tissues as required by the

Cuilleron disclosure. Applicant's argument that concentric rings somehow would prevent counter-clockwise rotation in the Cuilleron implant whereas spiral threading would not is not logical or persuasive. A spiral threading would provide a resistance to rotation as it is tightened in to place and the threads are loaded with compression forces from the bone..”

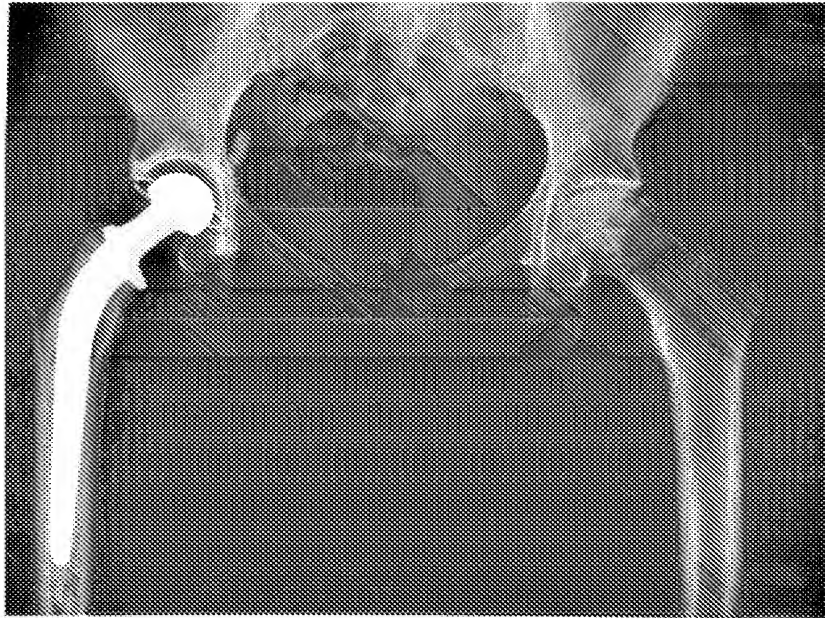
Applicant hereby respectfully invite the Examiner to note that Cuilleron '512's implant is intended to be used for hip implant, in which the upper rounded end (i.e., ball) of the implant as shown in Cuilleron '512's FIG. 5 is movably attached to an acetabular bone, and the lower tapered end of the implant is fixedly attached to a thighbone.

Below is an X-ray photo from Wikipedia ([http://en.wikipedia.org/wiki/Hip\\_replacement](http://en.wikipedia.org/wiki/Hip_replacement)) showing a hip implant implanted into a patient's right hip. As shown in the X-ray photo, the patient's right hip (left of image) has been replaced, with the ball of this ball-and-socket joint replaced by a metal head that is set in the thighbone or femur and the socket replaced by a white plastic cup (clear in this X-ray).

As can be seen in the photo, the relative orientation between the thighbone and the hip implant is crucial to the patient, as neither one of the thighbone and the hip implant is symmetrically formed. If the hip implant is not perfectly aligned with the right thighbone as is the left thighbone with the patient's own hip, the patient can not walk normally.

Therefore, Cuilleron '512's implant is intentionally formed with circumferential rings 1c, 2b in order to address the peculiarities of properly align the implant with the thighbone.

“Helical threads” have been known since the work of Archimedes. Cuilleron ‘512 knew about “helical threads.” But, because the implants of Cuilleron ‘512 are intended for movable



anatomical members, such as artificial limbs, the choice of symmetrical radial alignment between the circumferential rings 1c, 2b of Cuilleron ‘512 was deliberate in order to address the peculiarities and necessity of maintaining the implants within their receiving polyethylene cups, free of sympathetic rotation in response to the corresponding rotation of the attached artificial limb.

On the other hand, Applicant’s helical implant is for dental implant. In dental implant, the relative orientation of the implant and the bone is irrelevant to the implant design. Rather, the depth of the screwed implant in the bone is crucial. Therefore, Applicant’s dental implant may be formed with helical threads to facilitate the rotation of the implant into the jaw bone.

It is important to gain an understanding of the Examiner’s proposed combination to read the primary reference as teaching an increase in the surface area of contact (*i.e. pour multiplier*

*les surfaces en contact du cotyle (1) dan son logement)* by first inserting the artificial cotyle into a boring without preliminary tapping, and then packing the boring around the artificial cotyle *dans les tissus osseux*. This *tissus osseux* is customarily harvested from either a rib, or more commonly, from the hip of the patient. *Les tissus osseux*, unless it becomes infected, enables a post-operative growth of human bone around the artificial cotyle, thereby anchoring the artificial cotyle within the surrounding bone. The circular projections 1c and 2b, according to Cuilleron '512, better anchor the artificial cotyle 1 (that serves as a socket) and the artificial prostheses 2.

Neither artificial cotyle 1 nor the artificial prostheses 2 of the resulting artificial joint contemplate "helical" threads, despite the written assertion of Paper No. 200900511 that,

"Cuilleron discloses an implant having a cylindrical core (Figure 5) *with helical threads* (2b) for screwing the implant into the intramedullary channel of a prepared femur."

Paper No. 20090511 fails to make a *prima facie* showing of obviousness because the underlying factual basis for the Examiner's ultimate conclusion of obviousness, is false because Cuilleron '512 neither discloses nor suggests Applicant's *helical threads*. This rejection is therefore unsustainable on the evidence of record.

**Second**, the helically oriented thread would impermissibly prevent Cuilleron '512 from being used in its intended mode of operation to prevent sympathetic counter-clockwise rotation of the implant in response to rotation of its mating artificial limb. In essence, grafting helical treads onto the primary reference is the antithesis of what is critical in the teachings of the primary reference.

Neither artificial cotyle 1 nor the artificial prostheses 2 of the resulting artificial joint contemplate "helical" threads, and the resulting artificial joint is not, on the record of this

prosecution, improved by the presence of helical threads, despite the written assertion of Paper No. 20090511 that,

“Cuilleron discloses an implant having a cylindrical core (Figure 5) *with helical threads* (2b) for screwing the implant into the intramedullary channel of a prepared femur.”

Applicant respectfully observes that this assertion from Paper No. 20090511 is inaccurate, and is unsupported by the administrative record.

The Examiner is respectfully urged to pause and to consider whether the use of Applicant’s helical threads in either artificial cotyle 1 or the artificial prostheses 2, as substitutes for symmetrical radially aligned circumferential rings 1c, 2b of Cuilleron ‘512 would improve, or detrimentally impair the deliberate effort of Cuilleron ‘512 to address the peculiarities and necessitates for maintaining these implants free from sympathetic rotation in response to the corresponding rotation of the attached artificial limb? Applicant respectfully submits that the proposed combination, even if that combination would be medically feasible in a human bone, would not be an improvement upon the teachings of Cuilleron ‘512.

Accordingly, an implant formed with “helical thread” would prevent the Cuilleron ‘512 from being used in its intended mode of operation. This is persuasive evidence of the absence of obviousness in the pending claims.

**Third**, below is a list of recently issued U.S. patents and published U.S. patent applications in the related field regarding hip implants. None of these references discloses that “helical thread” may be formed on the femoral component of the hip implant.

| Patents or<br>Publication No. | Inventor(s) | Issued or<br>Published Date | Title |
|-------------------------------|-------------|-----------------------------|-------|
|-------------------------------|-------------|-----------------------------|-------|

|           |                    |                    |  |
|-----------|--------------------|--------------------|--|
| 7,713,306 | Gibbs              | May 11, 2010       | METHOD AND<br>APPARATUS FOR<br>ACETABULAR<br>RECONSTRUCTION                  |
| 7,682,398 | Croxton, et al.    | March 23, 2010     | VARIABLE GEOMETRY<br>RIM SURFACE<br>ACETABULAR SHELL<br>LINER                |
| 7,641,698 | Gibbs, et al.      | January 5, 2010    | MODULAR HIP JOINT<br>IMPLANT   |
| 7,608,112 | Kuczynski , et al. | October 27, 2009   | HIP ARTHROPLASTY<br>TRIALING APPARATUS<br>AND METHOD                         |
| 7,175,668 | Zweymuller         | February 13, 2007  | LEAFLIKE SHAFT OF A<br>HIP-JOINT PROSTHESIS<br>FOR ANCHORING IN THE<br>FEMUR |
| 7,074,241 | McKinnon           | July 11, 2006      | VARIABLE GEOMETRY<br>RIM SURFACE<br>ACETABULAR SHELL<br>LINER                |
| 6,942,702 | Mitsugi, et al.    | September 13, 2005 | STEM OF ARTIFICIAL HIP<br>JOINT  |



**(b) Cuilleron '512's "angled thread" is not synonymous with Applicant's "helical thread"**

In the Examiner's Answer mailed on 1 June 2010, the Examiner stated:

"First, appellant argues that the base reference to Cuilleron fails to teach the claimed limitation of "helical threads", but rather only discloses "spaced-apart concentric rings." The examiner simply disagrees. The supplied machine translation of the Cuilleron reference repeatedly states that the implant has "threading" (translation page 1, line 14; page 2, lines] and 28; page 3, line 5) and is "screwed in" (translation page 1, lines 1-2,6 and 9; page 2, line 17; page 3, line 20). Moreover the drawings illustrate spiral threading as illustrated below in the examiner annotation of Figure 5. In light of the disclosure referring to the implant being "threaded" and being "screwed in," as well as, the Figures which illustrate angled threads, one of ordinary skill in the art would reasonably interpret the reference as teaching "helical threads" as required by the present claims."

In addition, on page 8 of the Examiner's Answer mailed on 1 June 2010, the Examiner provided an adapted figure of Cuilleron '512's FIG. 5, which showed "angled threads" of Cuilleron '512's micro-threads. The adapted figure of Cuilleron '512 is further attached below.

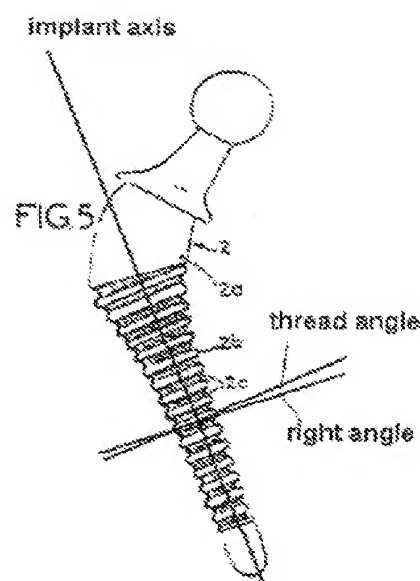
Applicant hereby respectfully submits that Cuilleron '512's "angled threads" as shown in the adapted FIG. 5 is a clear indicia that Cuilleron '512 does not teach "helical thread".

Specifically, as defined in Wikipedia (<http://en.wikipedia.org/wiki/Helix>), a "helix" is a type of space curve, i.e. a smooth curve in three-dimensional space, which is characterised by the fact that the tangent line at any point makes a constant angle with a fixed line called the axis.

Only because of this “constant angle” between the threads, the screw formed with the helical threads can be screwed easily into a bone structure.

On the other hand, in Cuilleron '512's implant, the angles formed between the micro-threads are not constant, with some of the micro-threads being parallel to each other, while some of the micro-threads forming an angle. Therefore, the micro-threads formed on Cuilleron '512's implant does **not** satisfy the definition of “helix”, or “helical thread”, which is characterised by the fact that the tangent line at any point makes a constant angle with a fixed line called the axis. Because the angles formed between Cuilleron '512's micro-threads are not constant, Cuilleron '512's implant can not be easily screwed into the bone structure due to a stronger resistance when the implant is rotated in the bone structure.

Therefore, the “angled threads” shown on Cuilleron '512's FIG. 5 proves that Cuilleron '512 fails to disclose “helical threading” as required by Applicant's claims 7, 13 and 19.



**(c) Cuilleron '512's implant can not be modified by Hansson '838 to have "continuous and repeated arcuate cross-sectional outlines"**

As best illustrated by the Table printed below, neither the Examiner's proposed combination nor Cuilleron '512 and Hansson '838, whether taken in various combinations or individually, teach Applicant's,

- core surrounded by helical threads,
- with the inclined flanks of said threads bearing a continuum of micro-patterns increasing ... ,
- the micro-patterns comprising one or more recesses and protrusions, and
- the micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns.

Specifically, the threads 9 of Hansson '838 bear neither Applicant's " flanks of ... threads" nor Applicant's " flanks of ... threads bearing a continuum of micro-patterns," and the pitch of the "thread" 9 of Hansson '838 is disclosed as 200 micrometer; consequently, "thread" 9 of Hansson '838 lacks a substrate structure able to support either Applicant's:

(a) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns"

or Applicant's,

(b) "micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-

patterns, two adjacent said recesses being separated by a distance on an order of 150  $\mu\text{m}$ .”

Applicant respectfully submits that the proposed combination, and Hansson '838, teaches nothing more than a series of threads 9 extending around a conically flaring portion 10.

In short, the administrative record establishes that “thread” 9 of Hansson '838 is unadorned with any sort of micro-patterns as defined by Applicant’s claims. These micrometer “differences” may not be ignored, either under the requirement of 35 U.S.C. §103(a) that all “differences” be considered, or under the explicit teachings of Cuilleron '512 and Hansson '838 of the crucial anatomical details necessary for the correct manufacture and use of their respective appliances. The fact that some aspects of Cuilleron '512 or Hansson '838 may bear some similarity to the definitions given by Applicant’s claims is immaterial to the issue of obviousness, particularly where neither reference teaches Applicant’s “*micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns, two adjacent said recesses being separated by a distance on an order of 150  $\mu\text{m}$ .*” In point-of-fact, the evidence introduced into the administrative record demonstrates that Cuilleron '512 fails to suggest either Applicant’s (a) “core surrounded by helical threads,” or Applicant’s (b) “core surrounded by helical threads, with the inclined flanks of said threads bearing a continuum of micro-patterns” and that Hansson '838 lacks Applicant’s “micro-patterns having continuous and repeated arcuate cross-sectional outlines throughout the entire length of the micro-patterns.”

The finding-of-fact set forth in Paper No. 20090511 that Cuilleron '512 “discloses an implant having a cylindrical cord (Figure 5) **with helical threads (2b)**” is fantasy, unsupported by a thorough reading of Cuilleron '512. As noted in the foregoing paragraphs, two observations

confirm this omission in Cuilleron '512: first, the perfection of the symmetry in the disposition of the cotyle 1 on both sides of the structures illustrated by Figures 1 and 5, and second, the absence of the adjective "helical" from the specification of Cuilleron '512. How can Cuilleron '512 be said to teach any peripheral structure except series of space-apart concentric rings if Cuilleron '512 itself does not use the adjective "helical?" The use of "threading" in the English language translation is simply that; "threading" is not synonymous with either "helical" or with "helical threading."

These omissions in the administrative record, together with the Examiner's recognition that Cuilleron '512 "does not explicitly disclose that said micro-patterns have **continuous and repeated arcuate cross-sectional outlines**," and the fact that the "threads" 9 of Hansson '838 can not simultaneously be said to constitute Applicant's (a) "helical threads" surrounding a core, or Applicant's (b) "micro-patterns formed on the flanks of helical threads," there is no *prima facie* showing of obviousness.

Applicant respectfully submits that neither Hansson '838's Figures 1, 2 or 3, nor the Examiner' proposed combination teach Applicant's "micro-patterns formed on the flanks of helical threads" because Hansson '838 teaches no adorned "flanks." In other words, Hansson '838, and thus the proposed combination, fails to teach Applicant's "micro-patterns formed on the flanks of helical threads;" and the proposed is an impermissible hindsight reconstruction of the art in the light provided solely Applicant's "micro-patterns formed on the flanks of helical threads" by Applicant's claims.

Given these deficiencies in the evidence introduced into the administrative record, the evidence does not support the Examiner's ultimate conclusion of law of obviousness. Withdrawal of this rejection is therefore, respectfully requested.

**(d) Cuilleron '512 and Hansson '838 can not be combined to teach Applicant's "*150  $\mu$ m between micro-threads*"**

One of the principal patentable distinctions between the pending claims and the prior art is that the combined prior art fails to teach or suggest Applicant's claims 7, 13 and 19's "*two adjacent recesses being separated by a distance on an order of 150  $\mu$ m*". This feature is defined by the pending claims, in terms of:

**Claim 7**, "two adjacent said recesses being separated by a distance on an order of **150  $\mu$ m**";

**Claim 13**, "two adjacent said recesses being separated by a distance on an order of **150  $\mu$ m**"; and

**Claim 19**, "the distance between the neighboring micro-patterns being approximately **150  $\mu$ m**".

It is patentably significant that in Paper No. 20090511, the Examiner explicitly admits that Cuilleron '512 fails to disclose a specific distance between each micro-pattern.

Paper No. 20090511 refers to Hansson '838 which teaches that the distance between adjacent threads may be approximately 0.2 millimeters (*i.e.*, approximately 200 micrometers ( $\mu$ m)), and alleges that,

"(m)erely providing for similar such spacing (e.g. 150  $\mu$ m) for the undisclosed spacing of the Cuilleron microthreads in order to promote rapid bone growth into the microthreading would have been obvious to one of ordinary skill in the art."

Additionally, page 9 of the Examiner's Answer state:

"Fourth, appellant argues that the applied references fail to teach the limitations in claims 7 and 13 that "said recesses being separated by a distance on an order of 150  $\mu$ m" and in claim 19 the limitation that "the distance between the neighboring micro-patterns being approximately 150  $\mu$ m." The examiner disagrees. As specified above in the rejection the examiner is of the position

that (1) the Hansson et al teaching of 200  $\mu\text{m}$  spacing meets the broadly claimed "on an order of 150  $\mu\text{m}$ " and "approximately 150  $\mu\text{m}$ " or alternatively, (2) the Hansson et al disclosure to space the micro-patterns at a distance to allow rapid bone growth and teaching that a 200  $\mu\text{m}$  spacing provides an appropriate distance would allow one of ordinary skill in the art to arrive at the claimed "approximately 150  $\mu\text{m}$ " through the routine optimization of the variable parameter."

Applicant respectfully disagrees with the Examiner's assertion because Applicant's "*150  $\mu\text{m}$  spacing between adjacent micro-patterns*" is not obtained by a merely routine testing. Rather, Applicant's "*150  $\mu\text{m}$  spacing*" is carefully selected in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

The absence of any teaching or suggestions in the evidence introduced into the administrative record of this prosecution history that (a) "*spacing between adjacent micro-patterns*" could be determined by routine testing, or (b) that "*spacing between adjacent micro-patterns*" is a controllable variable that would be a likely candidate for yielding both (i) adequate growth of the jaw bone tissue and (ii) maintain the largest possible surface contact area between the implant and the bond. These omissions from the prosecution history may not be ignored in view of the express command of the U.S. Congress set forth in 35 U.S.C. §103(a) that the "differences" between the subject matter sought to be protected by the pending claims and the prior art be identified, and that those differences be weighed against "the subject matter as a whole" before a conclusion-of-law on obviousness be made.

Specifically, as explained in Applicant's Amendment filed on 23 October 2008, Applicant's original specification explicitly discloses that the number of micro-patterns formed on the thread inclines is preferably to be as great as possible, because as the number of the

micro-patterns increased, the contact area of the implant is increased,<sup>1</sup> thereby enhancing the mechanical engaging force between the implant and the bone.<sup>2</sup> In order to increase the number of micro-patterns, the spacing between the micro-patterns should be decreased accordingly. On the other hand, Applicant's original specification also explicitly discloses that the size of the micro-patterns should be 100  $\mu\text{m}$  or more because a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100  $\mu\text{m}$ .<sup>3</sup> Accordingly, Applicant concludes that the micro-patterns should have a size of 150  $\mu\text{m}$ , in order to provide a micro-groove having enough size needed to grow the jaw bone tissue, while maintaining the largest possible surface contact area between the implant and the bone.

On the other hand, neither one of Cuilleron '512 and Hansson '838 has recognized the need for providing a micro-groove both having (i) enough size needed to grow the jaw bone tissue, while (ii) maintaining the largest possible surface contact area between the implant and the bone. As explicitly admitted by the Examiner, Cuilleron '512 fails to disclose a specific distance between each micro-pattern, and Hansson '838 merely discloses that the distance to the adjacent microthread may be 200  $\mu\text{m}$ . Hansson '838's 200  $\mu\text{m}$  is different from Applicant's 150  $\mu\text{m}$  by more than **30 percent**. Table I illustrates these deficiencies in the administrative record:

| Present invention | Cuilleron '512                          | Hansson '838   |
|-------------------|---|--|
| a core            | an anchoring threading for bone implant | a dental implant having a conically flaring portion 10 |

<sup>1</sup> Page 6, lines 3-5 of Applicant's original specification reads: "Meanwhile, as **the number of the patterns** is increased, **the contact area** of the implant is also remarkably **increased**, whereas time for machining the patterns is also extended."

<sup>2</sup> Page 3, lines 25-30 of Applicant's original specification reads: "The present invention has been made to solve the above problems, and it is an object of the present invention to provide a helical implant, which is formed with a micro-pattern on thread inclines of the helical implant, so that **a contact area and a engaging force between the implant and the jaw bone can be increased**, and so that stress concentration can be restricted, thereby dispersing a physiological load."

<sup>3</sup> Page 5, lines 23-25 of Applicant's original specification reads: "... since a micro-groove needed to grow the jaw bone tissue has a minimum size of about 100  $\mu\text{m}$ , the pattern must be formed to have a size of 100  $\mu\text{m}$  or more, preferably 150  $\mu\text{m}$ ."



|  |  |  |
|--|--|--|
| surrounded by helical threads  |  |  |
| <b>micro-patterns</b> formed on  | <b>micro threads (1f, 2c)</b>                              | <b>micro-threads 9</b>   |
| the flanks of helical threads  |  |  |
|  | formed on the surface of the<br>threading (1c)             | formed on the surface of<br>conically flaring portion 10   |
| with the micro-patterns<br>comprising one or more<br>recesses and protrusions, and                                 |  |  |
| two adjacent said recesses<br>being separated by a distance<br>on an order of <b>150 <math>\mu\text{m}</math>.</b> | micro threads<br>in the dimension of<br><b>micrometers</b> | the distance between adjacent<br>micro-threads 9 may be <b>200<br/><math>\mu\text{m}</math>.</b> |

It is doubtful, in view of the foregoing noted deficiency in the evidence present in the administrative record, that there is evidence which would permit an inference that one with ordinary skill in the art will combine Hansson '838 and Cuilleron '512 to reach Applicant's "150  $\mu\text{m}$  spacing."

Paper No. 20090511 reached a further conclusion of law about the obviousness *vel non* of the subject matter defined by Applicant's pending claims, namely that,

"the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of **routine testing** obvious to the ordinarily skilled artisan",

and

"Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of **routine practice**".

This conclusion of law is in not in conformance with the more realistic and earlier statement by Thomas A. Edison, that:

“Genius is one percent inspiration, ninety-nine percent perspiration.”

The laborious and routine testing denigrated by Paper No. 20090511 is, to the contrary, exactly what Thomas Edison said constitutes an invention. To further buttress the Examiner’s conclusions of law, Applicant respectfully submits that in actuality, (a) only by unduly tedious and laborious experimentation would an artisan of ordinary skill in the art be able to identify which dimension or spacing would be suitable candidates for consideration for use in Applicant’s helical implant, and (b) only by further unduly tedious and laborious experimentation would an artisan of ordinary skill in the art be able to obtain,

*“two adjacent recesses being separated by a distance on an order of 150  $\mu\text{m}$ ”*

recited by Applicant’s claims 7, 13 and 19. This recognition of the necessity for “***routine testing***” which the Examiner has introduced into the administrative record, is the hallmark of non-obviousness under 35 U.S.C. §103(a).

In the Examiner’s Answer mailed on 1 June 2010, the Examiner further stated:

“One desiring to practice the Cuilleron invention would have to determine the spacing of the microthreads 2e on their own accord since Cuilleron is silent on the issue, Hansson et al teach that for similar microthreads in a bone implant a spacing of around 200  $\mu\text{m}$  is desirable because it provides for rapid bone growth, Merely, selecting similar spacing for the Cuilleron micro threading would have been obvious to the ordinarily skilled artisan in view of the Hansson et al teaching.

Finally, appellant's quotation of Thomas Edison that "Genius is one percent inspiration, ninety-nine percent perspiration" while perhaps inspiring, has little to do with the statutory requirements for protecting intellectual property. The Supreme Court rejected the "sweat of the brow" doctrine even for the minimal originality requirement in copyrights, See *Feist Publications v, Rural Telephone Co*, 499 U.S. 340 (1991).”

Applicant respectfully disagrees with the Examiner because the Supreme Court's rejection of the "sweat of the brow" doctrine is irrelevant to the current issue of the present application.

Specifically, the "sweat of the brow" doctrine is related to the copyright law, in which an author gains rights through simple diligence during the creation of a work, such as collecting information. For the "sweat of the brow" doctrine, substantial creativity or "originality" is not required.

This is not the case for Applicant's invention. As discussed previously, the Inventor of the present invention initiated to find a controllable variable that would both *(i)* obtain adequate growth of the jaw bone tissue and *(ii)* maintain the largest possible surface contact area between the implant and the bond. On the other hand, neither Cuilleron '512 nor Hansson '838 discloses, or even teaches or suggests that the spacing between the micro-threads can be optimized to obtain better implant result.

Therefore, the Inventor of the present invention is equipped with "creativity" and "originality", and the "creativity" and "originality" is embodied as claims 7, 13 and 19's *"two adjacent recesses being separated by a distance on an order of 150  $\mu\text{m}$ "*.

Accordingly, claims 7, 13 and 19's *"two adjacent recesses being separated by a distance on an order of 150  $\mu\text{m}$ "* is patentably distinguishable over the combined prior art.

## SUMMARY

Although the issues here concern obviousness, Applicant respectfully submits in view of the careful statements written by the Commissioner in *Ex parte Frye* (26 February 2010) about the *standard of review* of questions of anticipation and of obviousness, that when weighing the accuracy of the Examiner's determination-of-law on the issue of obviousness, full consideration must be given to the recent statements by the Director of the U.S.PTO made in reversing the Examiner's final rejection under 35 U.S.C. §102(b) in the *Precedential Opinion*, written in *Ex parte Frye* (26 February 2010),

"[t]o establish anticipation, every element and limitation of the claimed invention must be found in a single prior art reference, **arranged as in the claim.** *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1383 (Fed. Cir. 2001)" (Emphasis added)

The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art and (2) any differences between the claimed subject matter and the prior art, the conclusion of obviousness here may not be sustained upon such conclusory findings-of-facts as:

"Cuilleron discloses an implant having a cylindrical core (Figure 5) *with helical threads* (2b) for screwing the implant into the intramedullary channel of a prepared femur."

or,

"the mere testing of similarly sized spacings in order to find the most optimal spacing is not of no patentable merit, but rather the result of **routine testing** obvious to the ordinarily skilled artisan",

and

“Merely, selecting similar spacing for the Cuilleron microthreading would simply be obvious to the ordinarily skilled artisan as a matter of **routine practice**”.

These erroneous underlying findings-of-fact pervade the Examiner’s conclusion of obviousness.

As is noted in the foregoing paragraphs, the absence of *every element* and *every limitation* found among the teachings of the proposed combination, and the failures noted in the foregoing paragraphs of the proposed combination to teach *every element* and *every limitation arranged as in the claim* in conformity with the manner defined by Applicant’s claims, and as is suggested by the Director in the *Precedential Opinion*, written in *Ex parte Frye* (26 February 2010), is persuasive evidence of an absence of obviousness *vel non* under 35 U.S.C. §103(a).

The proposed combination of Cuilleron ‘512 and Hansson ‘838 is an impermissible hindsight reconstruction of the art in the light provided solely Applicant’s “micro-patterns formed on the flanks of helical threads” by Applicant’s claims, that is inimical to the structure, and mode of operation for that structure, taught by Cuilleron ‘512. This is the antithesis of obviousness, and fatally undermines the Examiner’s ultimate conclusion of obviousness.

For these reasons, Applicant believes that the rejection is improper and should be withdrawn.

Respectfully submitted,

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